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APPLICATION NO. 09/058,505	FILING DATE 04/10/99	FIRST NAMED INVENTOR KIMBER	ATTORNEY DOCKET NO. 138.41.US01
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EXAMINER ADAMS, D

ART UNIT 1618	PAPER NUMBER 9
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DATE MAILED: 10/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/058,589

Applicant(s)

Kimber, et al.

Examiner
Donald E. Adams, Ph.D., J.D.

Group Art Unit
1617



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-19 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Please Note: A Fax Response Pilot for Written Restriction Requirements was adopted in an effort to enhance communication with our customers and reduce processing time. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

15. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1, ~~and~~ ^{§ 11.19} 5-7, drawn to a method of *inhibiting* the inflammatory activity of IL-1 β , classified in Class 514, subclass 12.
- II. Claims 2-4, drawn to a composition that *produces a local inflammatory reaction* comprising lactoferrin and a therapeutic or cosmetic compound, classified in Class 514, subclass 12.

16. The Inventions are distinct, each from the other because of the following reasons:

17. Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the claimed invention of Group I does not require the therapeutic or cosmetic compound *that produces a local inflammatory reaction* as required by the claims of Group II.

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their recognized divergent subject matter, they represent an undue burden on the examiner and restriction for examination purposes as indicated is proper.

19. If applicant elects the Invention of Group I, the further species election is required. The application contains claims directed to the following patentably distinct species of inflammatory disorders:

- A. Arthritis, claim 11
B. Pulmonary inflammatory disease, claim 11
C. Dermal inflammatory disorder, claim 12
D. Contact dermatitis, claim 13
E. UV-induced inflammation, claim 13
F. Infant diaper rash, claim 13
G. Acne, claim 13

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- H. Facial skin aging, claim 14
- I. Asthma, claim 15
- J. Sinusitis, claim 16
- K. Rhinitis, claim 17
- L. Bronchitis, claim 18 and 19

The species differ with respect to their etiology and locus.

20. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, and 5-10 are generic.

21. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

22. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

23. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

24. A telephone call was made by Pamela Webber to Mr. Halluin on September 10, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

25. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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27. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams, Supervisory Patent Examiner whose telephone number is (703) 308-0570. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiners voice mail service. The fax phone number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

September 29, 1999



Donald E. Adams, Ph.D., J.D.
Supervisory Patent Examiner
Technology Center 1600



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
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IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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